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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/673,380	09/30/2003	Takashi Nakagawa	031729	4353

38834 7590 10/16/2007

WESTERMAN, HATTORI, DANIELS & ADRIAN, LLP
1250 CONNECTICUT AVENUE, NW
SUITE 700
WASHINGTON, DC 20036

EXAMINER	
WEGERT, SANDRA L	

ART UNIT	PAPER NUMBER
1647	

MAIL DATE	DELIVERY MODE
10/16/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/673,380	NAKAGAWA ET AL.	
	Examiner	Art Unit	
	Sandra Wegert	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 September 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6* is/are pending in the application.

4a) Of the above claim(s) *6* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 5* is/are rejected.

7)☒ Claim(s) *4* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/28/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments, and/or Claims

The amendment and Arguments, filed 9 July 2007, and the Information Disclosure Statement, filed 28 September 2007, have been entered. Citations in the Information Disclosure Statement that have been cited in prior IDS's have been lined-through by the examiner.

Claims 1, 4, 5 and 6 have been amended. Claims 6 has been withdrawn by the examiner.

Claims 1-5 are under examination.

Withdrawn Objections and/or Rejections

Informalities-

The objection to the Specification for not complying with the requirements of 35 USC § 120 is *withdrawn*. Applicants amended the first paragraph of the Specification to refer to the prior application.

Claim Rejections-35 USC § 112, first paragraph –Lack of Enablement and "Prevention."

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of Claims 1-5 under 35 USC § 112, first paragraph, for total lack of

enablement is *withdrawn*. This rejection is now a Scope of Enablement rejection over claims 1-3 and 5 (see Rejection below). The rejection was made in the previous office action (7 February 2007, pp. 3-5) because the evidence presented seemed to indicate that PAR-2 knockout animals were used for the experiments, which precluded PAR-2's involvement in the kidney diseases being treated. Applicants have argued (9 July 2007, p. 6) that one experiment did use normal animals with an experimental glomerulonephritis (see Figure 4), thus confirming that the treatment is at least partially enabled.

Additionally, the claims are enabled for methods of using PAR-2 ligands in addition to SLIGRL-NH2. Evidence presented by the applicants describes several PAR-2 ligands, some of which are enzymatically-stable short peptides (9 July 2007, p. 9-10).

Furthermore, the rejection of Claim 1 under 35 USC § 112, first paragraph, over the issue of "preventing" is *withdrawn*. Applicants amended Claim 1 to remove wording related to the prevention of kidney diseases. (9 July 2007).

Written Description.

The rejection of Claims 1-5 under 35 U.S.C. 112, first paragraph, for lack of written description is *withdrawn* based on Applicants' arguments. The rejection was made in the previous Office Action (9 July 2007, pp. 6-7) because the claims recite use of a "PAR-2 activating agent." Applicants have argued that they were in possession of several PAR-2 activating agents and also cite references in which several different PAR-2 agonists are disclosed (see, for example, references 1-4 in the Information Disclosure Statement of 28 September 2007).

New/Maintained Objections and Rejections

Objections-

Claim 4 is objected to for depending from a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

35 USC § 112, First Paragraph – Scope of Enablement

Claims 1-3 and 5 are rejected under 35 U.S.C. 112, first paragraph, because the Specification, while being enabling for methods of using PAR-2 agonists to treat rapidly-progressive glomerulonephritis as well as crescentic glomerulonephritis, does not reasonably provide enablement for use of PAR-2 agonists to treat other kidney diseases. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Claims 1-3 and 5 are drawn to a method of treating kidney diseases by administering a composition comprising a PAR-2 activating agent. Dependent claims recite primary and secondary kidney diseases as well as examples of known PAR-2 activating agents.

The specification discloses using PAR-2 ligands to treat an experimental glomerulonephritis in mice. The glomerulonephritis was produced by injecting the mice with an antibody generated against the glomerular basement membrane. Data are presented that link the experimental glomerulonephritis with elevated secretion of serum albumin. This elevated albumin secretion by the animals' kidneys was partially attenuated by administration of several

PAR-2 ligand peptides.

However, a sufficient amount of direction or guidance is lacking in claims 1-3 and 5. The claims embrace treatment of any kidney disease by injecting a PAR-2 activating agent. However, the Specification only provides a nexus between the PAR-2 receptor and glomerulonephritis. Applicants have found that PAR-2 ligands are protective of the specific damage produced by destruction of the glomerular basement membrane, defined as glomerulonephritis (Specification, pp. 2, 6 and 9, for example). However, a search of the literature shows that it is doubtful if other kidney diseases are a result of- or have as their primary symptom- glomerular basement membrane destruction. For example, diabetic nephropathy, polycystic kidney disease, cancer, glomerular hypertension, glomerular hypertrophy, kidney stones, and renal hyperlipidemia all probably involve etiologic mechanisms that do not involve PAR-2, or the destruction the glomerular basement membrane.

Applicants argue that evidence from the instant Specification and indirect evidence from the literature shows that PAR-2 receptors play a role in glomerulonephritis. They further argue that data from certain species of nephritic rats and PAR-2 knockout mice can be applied to glomerular nephritic diseases in humans (Arguments, pp. 8 and 9). The examiner agrees that glomerulonephritis involves PAR-2 receptors, and that data from rodents can be applied to humans. However, PAR-2's role in other *kidney diseases*, with seemingly different underlying etiologies, has not been sufficiently demonstrated in the instant Specification or presented by applicants' arguments.

Conclusion

Claim 4 is objected to. Claims 1-3 and 5 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Wegert whose telephone number is (571) 272-0895. The examiner can normally be reached Monday - Friday from 9:00 AM to 5:00 PM (Eastern Time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Manjunath Rao, can be reached at (571) 272-0939.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent

Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (in USA or CANADA) or 571-272-1000.

SLW
9 October 2007

/Elizabeth C. Kemmerer/

Primary Examiner, Art Unit 1646